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United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/071,405 Filing Date: February 08, 2002

Appellant(s):

William S. Francos, Reg. No. 38,456

For Appellant

Supplemental EXAMINER'S ANSWER

This is in response to the appeal brief filed September 10^{th} , 2008 appealing from the Office action mailed July 2^{nd} 2008.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The statement of the status of claims contained in the brief is correct.

NEW GROUNDS OF REJECTION

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Claim 7 is directed to a system and is newly rejected under 35 U.S.C. 101, 112 2nd paragraph and 112 1st paragraph.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,825,908	PIEPER et al.	10-1998
5.457.754	HAN et al.	10-1995

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows (see also MPEP 2106):

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material". In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and

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Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPO2d at 1035.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 7 defines a "system". However, while the preamble defines a "system", which would typically be indicative of an "apparatus", the body of the claim lacks definite structure indicative of a physical apparatus. Furthermore, the specification indicates that the invention may be embodied as pure software since there is do defining structure listed. Rather various operations are described which are performed as software functions. Therefore, the claim as a whole appears to be nothing more than a "system" of software elements, thus defining functional descriptive material per se.

Functional descriptive material may be statutory if it resides on a "computerreadable medium or computer-readable memory". The claim(s) indicated above lack
structure, and do not define a computer readable medium and are thus non-statutory for
that reason (i.e., "When functional descriptive material is recorded on some computerreadable medium it becomes structurally and functionally interrelated to the medium
and will be statutory in most cases since use of technology permits the function of the

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descriptive material to be realized" – Guidelines Annex IV). The scope of the presently claimed invention encompasses products that are not necessarily computer readable, and thus NOT able to impart any functionality of the recited program. The examiner suggests:

- Amending the claim(s) to embody the program on "computer-readable medium" or equivalent; assuming the specification does NOT define the computer readable medium as a "signal", "carrier wave", or "transmission medium" which are deemed non-statutory; or
- Adding structure to the body of the claim that would clearly define a statutory apparatus.

Any amendment to the claim should be commensurate with its corresponding disclosure.

Note:

"A transitory, propagating signal ... is not a "process, machine, manufacture, or composition of matter." Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101; thus, such a signal cannot be patentable subject matter." (*In re Nuijten*, 84 USPQ2d 1495 (Fed. Cir. 2007)).

Should the full scope of the claim as properly read in light of the disclosure encompass non-statutory subject matter such as a "signal", the claim as a whole would be non-statutory. Should the applicant's specification define or exemplify the computer readable medium or memory (or whatever language applicant chooses to recite a

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computer readable medium equivalent) as statutory tangible products such as a hard drive, ROM, RAM, etc, <u>as well as</u> a non-statutory entity such as a "signal", "carrier wave", or "transmission medium", the examiner suggests amending the claim to <u>include</u> the disclosed tangible computer readable storage media, while at the same time <u>excluding</u> the intangible transitory media such as signals, carrier waves, etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112 first <u>and</u> second paragraphs as attempting to define a product (i.e., system) entirely by virtue of its function, in the absence of any recited structure.

Products must distinguish over the prior art in terms of their structure (or structure + structure's function when claimed functionally) rather than function alone (MPEP 2114). Therefore, an "apparatus" not having structural limitations fails to "particularly point out and distinctly claim ..." the invention in accordance with 35 U.S.C. 112, 2nd paragraph.

Furthermore, while the specification disclosure may be enabling for a plurality of structural elements performing the claimed functions [1], the specification does not reasonably provide enablement for a single structural element (or no structural elements) performing all of the claimed functions. That is, given the claim in question,

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the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims ("A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph" because a single means claim covers "every conceivable means for achieving the stated purpose" and "the specification disclosed at most only those means known to the inventor" - MPEP, at paragraph 2164.08(a)).

Applicant is advised to define the apparatus by virtue of the individual structural element that serve to perform the individual functions recited in the corresponding method claim.

[1] Even when an apparatus is disclosed as being computer implemented (e.g., software implemented on hardware), the requirement remains that there be some structure recited in the body of the claim (e.g., a processor and a memory storing a program which when implemented performs the method steps). For purposes of "means plus function" language, individual disclosed steps corresponding to computer program elements operating on a processor (e.g., inputting, filtering, detecting and resolving) may be considered as separate means (*Dossel*, 115 F.3d at 946–47, 42 USPQ2d at 1885).

GROUNDS OF REJECTION ARGUED ON APPEAL

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

 Claims 1, 4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,825,908 to Pieper et al.

With regard to claim 1, Pieper discloses a method of processing images, in which individual images succeed one another in a direction of succession (Figs. 3 and 13),

a multi-dimensional data set is constructed from the individual images (column 9, lines 1-10),

which multi-dimensional data set assigns data values to positions in a multidimensional space (column 9, lines 1-10),

which multi-dimensional space is set up by the direction of succession and two directions parallel to the surface of the individual images (Fig. 3 and column 9, lines 35-50),

a slice through the multi-dimensional data set is reconstructed along a cut plane through the multi-dimensional space (Fig. 13 and column 14, lines 19-35), and

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the direction of the cut plane has a component in the direction of succession, and in which a region of interest is located on the basis of the cut plane (Fig. 13 and column 14, lines 27-35 and column 9, lines 38-42).

segmenting a region of interest from the one or more relevant images is performed in one or more of the individual images, wherein the segmenting is performed on the basis of information in the reconstructed slice along the cut plane through the multi-dimensional data set (column 17, lines 15-35).

Locating an edge in the reconstructed slice, wherein the segmenting in the region of interest in the one or more images is performed on the basis of the location of the edge found in the relevant (image) (column 14, lines 25-37).

Pieper does exactly what is claimed. The whole purpose of the invention of Pieper is to create reconstructed image slices in a direction different from the sampled image slices (column 14, lines 25-37). Pieper teaches that images are generated or reconstructed using data from slice images in a different direction through well known techniques known in the art. These techniques most likely use interpolation for recreating an image from a series of slice images. It is also a primary object of Pieper's invention to identify anatomical structures or regions of interest in both multiple interesting slices and in the 3D model image data (column 14, lines 56-67 and column 15, lines 22-63). Pieper teaches that markers are used in the image and the location of the marker is known in the other corresponding 2D slices and the 3D model image which are all simultaneously displayed to the user or physician. Furthermore when an object or anatomical structure or region of interest is identified in one 2D slice, it is

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identified in the other corresponding 2D slices, which have been reconstructed or generated (column 15, lines 48-63). Therefore Pieper teaches a comprehensive system of 3D modeling with both sampled reconstructed 2D slices to identify regions of interest such as anatomical structures, markers, blood vessels or any other object. It should be noted that edges are inherently identified when the anatomical structure or object of interest is identified in the corresponding 2D slices. There can be no object of interest or anatomical structure without the known location of identified edges which define such a structure.

With regard to claim 4, Pieper discloses a method of processing images as claimed in claim 3, in which respective slices through the multi-dimensional data set are reconstructed along a plurality of cut planes through the multi-dimensional space, and the directions of the individual cut planes have components in the direction of succession individual edges are tracked in the individual slices, and the segmentation of the region of interest in the one or more images is performed on the basis of the individual locations of the respective edges found in the relevant image (Fig. 13 and column 14, lines 27-35 and column 9, lines 38-42).

With regard to claims 7, 8 and 9 the discussion of claim 1 applies.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieper in view of U.S. Patent 5.457,754 to Han et al.

With regard to Claim 5, Pieper discloses a method of processing images as claimed in claim 4. Pieper discloses the finding the boundaries of a region of interest and also discloses interpolation with respect finding a center-line thru use of interpolation but does not explicitly teach the use of interpolation for finding the edges between slice portions. However, it can be assumed that in order to create a 3D model as taught by Pieper that some interpolation will be needed to construct a model with smoothed contours of an organ or other region of interest for example. Han discloses a method for automatic contour extraction of a cardiac image in which:

 A boundary of the region of interest is derived by interpolation between the individual locations in the relevant image of the respective edges found (col. 16 lines 19-23). [Interpolation is used to create a continuous boundary as shown in Figures 28a, 28b, and 28c.]

It would be obvious to one skilled in the art to modify Pieper with the process of interpolation as taught by Han because Pieper stresses the importance of accurately

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determining the contours. Furthermore one would be motivated to make this modification to improve the accuracy of the boundary because as Han explains noise and discontinuities negatively impact the determining of the boundary. Han explains how interpolation is used in medical imaging, specifically of the heart, to account for these factors.

With regard to claim 6, Han discloses a method for automatic contour extraction of a cardiac image in which:

The interpolation is performed inter alia on the basis of a priori information concerning the region of interest (23-26). [The a priori information is used to ensure the contours are not just continuous but meaningful as well.]

(10) Response to Argument

I. Rejection of claims 1, 4 and 7-9 under 35 U.S.C. 102(b) in view of Pieper, et al.

a. Prima Facie case of anticipation not established based on Pieper et al.

With regard to independent claims 1, 7 and 8, Applicant argues primarily the claimed features of:

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Locating an edge in the reconstructed slice, wherein the segmenting in the region of interest in the one or more images is performed on the basis of the location of the edge found in the relevant (image)

Specifically Applicant argues that because Pieper does not explicitly discuss edges in identifying structures in reconstructed 3D slice images, that edges are not disclosed. Examiner disagrees. The whole purpose of the invention of Pieper is to create reconstructed image slices in a direction different from the sampled image slices (column 14, lines 25-37). Pieper teaches that images are generated or reconstructed using data from slice images in a different direction through well known techniques known in the art. These techniques most likely use interpolation for recreating an image from a series of slice images. It is also a primary object of Pieper's invention to identify anatomical structures or regions of interest in both multiple interesting slices and in the 3D model image data (column 14, lines 56-67 and column 15, lines 22-63). Pieper teaches that markers are used in the image and the location of the marker is known in the other corresponding 2D slices and the 3D model image which are all simultaneously displayed to the user or physician. Furthermore when an object or anatomical structure or region of interest is identified in one 2D slice, it is identified in the other corresponding 2D slices, which have been reconstructed or generated (column 15, lines 48-63).

Therefore Pieper teaches a comprehensive system of 3D modeling with both sampled reconstructed 2D slices to identify regions of interest such as anatomical structures, markers, blood vessels or any other object. It should be noted that edges are inherently identified when the anatomical structure or object of interest is identified

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in the corresponding 2D slices. There can be no object of interest or anatomical structure without the known location of identified edges which define such a structure. Indeed there is no structure to be identified without edges that define such structures.

Applicant argues that identifying edges is not inherent to identifying structures in images and that Examiner has not properly established inherency. The question remains then, how does Pieper identify structures in the 3D reconstructed images without edges? The answer is that it is impossible to identify or a structure without identifying the edges that define the structure. Applicant is encouraged to provide an example of how a structure might be identified in 3D reconstructed image without identifying edges defining the structure.

Applicant further argues that even if edges are located are located as Examiner asserts and Pieper disclose this, that the edges are not used as described in the claim. Applicant argues that the edges shown in all of the figures of Pieper are not used as disclosed: wherein segmenting in the region of interest in the one or more images is performed on the basis of the location of the edge found in the relevant (image).

Examiner asserts that regions of interest and the structures identified in the reference to Pieper are segemnted according to the structure of the regions of interest. The structure of the regions of interest are defined by the edges that shape the structures or regions of interest. This is the whole purpose of taking 3D medical images. Edges are identified that define certain biological structures and those biological structures are examined. The identified structures themselves are regions of interest which are defined by the edges.

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b. Inherency not established

In response to Applicant's inherency arguments, it should be clear that edges defining the biological structures in the images disclosed by Pieper also define the regions of interest. Edges must be inherently determined in order to identify structures and objects in images and it is those structures and objects that are used to determine a region of interest. This is especially true in the art of biological 3D imaging and especially significant in the reference to Pieper. Piepers invention is directed to the exact same purpose as the presently claimed invention. The purpose is to examine 3D biological structures, which are inherently defined by their edges and the structures define the regions of interest. Pieper disclose the claimed features as recited and the rejection in view of Pieper is maintained.

c. The Advisory Action makes assertions not supported by the applied art

Appellant argues that Examiner uses conjecture and unsupported assertions.

Examiner disagrees. Examiner merely discusses well known and relavent techniques in

the art. Examiner submites that the rejection in view of Pieper stands on its own merits.

The disucssuion of well known fundamental techniques of reconstruction are made for

Applicant's benefit and the benefit of the record.

Appelant also argues that Examiner makes unsupported assertions regarding the absolute need fror known locations of identified edges. The technique disclose by Pieoer has been disclosed above with regard for the need to identify edges which define

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structure in an image and define regions of interest in medical imaging. Examiner is not making unsupported assertions. Examiner is stating facts well known by those of ordinary skill in the art. If Appellant knows of a way to identify objects and structure in 3D images that does not involve identifying a correlating located edges then Appellant is encouraged to provide a counter example to Examiner's discussion of inherency regarding identifying edges in 3D images.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within TWO MONTHS from the date of this answer exercise one of the following two options to avoid *sua sponte* dismissal of the appeal as to the claims subject to the new ground of rejection:

(1) Reopen prosecution. Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR Art Unit: 2624

41.39(b)(1) will be entered and considered. Any request that prosecution be reopened

will be treated as a request to withdraw the appeal.

(2) Maintain appeal. Request that the appeal be maintained by filing a reply

brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of

rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the

other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR

41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be

treated as a request that prosecution be reopened before the primary examiner under

37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO

MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to

reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex

parte reexamination proceedings.

Respectfully submitted,

/Wes Tucker/

Examiner, Art Unit 2624

A Technology Center Director or designee must personally approve the

new ground(s) of rejection set forth in section (9) above by signing below:

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Conferees:

/Brian P. Werner/

Supervisory Patent Examiner, Art Unit 2624

/Matthew C Bella/

Supervisory Patent Examiner, Art Unit 2624